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(71) Applicant (for all designated States except AU BB CA GB IE LK MN MW NZ SD): UNILEVER N.V. [NL/NL]; Weena 455, NL-3013 AL Rotterdam (NL).

(71) Applicant (for AU BB CA GB IE LK MN MW NZ SD only): UNILEVER PLC [GB/GB]; Unilever House, Blackfriars, London EC4 4BQ (GB).

(72) Inventors: TIJBURG, Lilian, Bernadette, M.; Rietkraag 27, NL-3121 TC Schiedam (NL). WESTSTRATE, Jan, Adriaan; Boompjes 287, NL-3011 XZ Rotterdam (NL).

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(54) Title: ANTIOXIDANT COMPRISING FOOD PRODUCTS

(57) Abstract

The invention concerns a food product which is part of the common food habits of consumers and which comprise antioxidants and/or antioxidant vitamins in amounts sufficient to significantly increase the antioxidant status in the human blood plasma, and by which the consumer need not alter its daily food habits, while the risk towards atherosclerosis can be reduced by the intake of the food product. Accordingly, a contribution towards a healthy diet is provided although no longer supplements such as tablets or specially selected diet needs to be taken. Examples of suitable food products comprising the components in accordance with the invention are fat based food products which form part of the daily diet, such as margarine, halvarine or any other spread; dressings such as mayonnaise, tomato ketchup, and salad dressings; cheese products such as cheese, cheese spreads and cheese sauce; sauces; cream, ice cream and the like.

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Antioxidant comprising food products

The present invention concerns a food product comprising natural components which increase the antioxidant status in the blood plasma of the consumer if the food product is used according to the common food habits of the consumer.

A high intake of antioxidants has been associated with a decreased risk of cardiovascular disease. Experimental evidence has been published on the basis of which it is assumed that oxidation of lipoproteins is an important step in atherosclerosis and that antioxidants may protect lipoproteins from oxidation. Atherosclerosis is seen as an important cause of death in the Western society.

Food products comprising low levels of components which in themselves are capable of increasing the antioxidant status in the blood plasma of humans are known. Examples of such potential antioxidant components are α-tocopherol (vitamin E), ascorbic acid (vitamin C), and β-carotene. E.g., such components are present in many food products which comprise these components as a natural ingredient. Also, food products to which such components have been added are available on the market. Also the use of such components as separate supplements to the human diet, e.g. in the form of tablets or capsules is known.
The daily intake of the amounts needed for antioxidant increase is relatively high compared to what is found in food products which comprise no added antioxidants, and none of the food products presently known comprises levels of antioxidants sufficient to significantly increase the antioxidant level in the blood plasma upon the common, average amount of daily intake of the food product except for eating very high amounts of fruits and vegetables.

Accordingly, the intake of such high amounts could, up till now, be taken care of by the intake as a supplement to the

human diet (e.g., by the intake of tablets or the like), or by a specially selected diet.

Consumers these days have a clear preference for food products which form part of their common food habits and which, in themselves, have a clear contribution towards a healthy diet by which no longer additives or a special diet needs to be taken.
The present invention concerns a food product by which this desire can be met. In particular, the present invention aims to provide a food product which is part of the common diet and which comprises antioxidants and/or antioxidant vitamins in amounts sufficient to significantly increase the anti-oxidant status in the human blood plasma. By this invention, the consumer needs not alter his daily consuming habits, while the risk towards atherosclerosis can be reduced by the intake of the food product.
Examples of suitable food products comprising the components in accordance with the invention are fat based food products which form part of the daily diet, such as margarine, halvarine or any other spread; dressings such as mayonnaise, tomato ketchup, and salad dressings; cheese products such as cheese, cheese spread and cheese sauce; sauces; cream, ice cream and the like.
Preferably, the food product of the invention is a spread, dressing, sauce or ketchup.

It is preferred to apply the antioxidant components in products which are used on a daily bases, such as a spread. In that case, the highest benefit is obtained from the present invention. In a further preferred embodiment of the invention, the food product is a yellow fat spread which can comprise 0 (zero) to 90% fat (usually 5-80%).
In another preferred embodiment, the food product is a sauce, e.g. a tomato based sauce, or a ketchup such a tomato ketchup.

The food products as such are common products in the Western world, and are used by consumers on a daily basis in amounts different for each individual. Figures of the average amounts referred to are available to the man skilled in the art.

In this specification, an antioxidant is any substance that, when present at low concentrations compared to those of an oxidizable substrate in the human body, significantly inhibits free radical chain reactions of that oxidizable substrate in the human body. In this specification, where the term antioxidant is used without specifically also mentioning antioxidant vitamin, both antioxidant and antioxidant vitamins are meant.

The amounts to be used in a particular food product are to be chosen such that a significant increase in antioxidant level in the blood plasma of humans is found. The present invention preferably concerns the use of moderate amounts of antioxidants, which means more than the low amounts found in the known products comprising these components is present, but less than about 10 times the lowest amount that provides a significant increase of antioxidant status in the blood plasma. This is much less than what is found in the several publications in which pharmacological amounts are recommended. It has been found that the addition at much lower levels can provide a reduced risk towards atherosclerosis.
The amounts are to be determined on the basis of the average regular or daily intake of the specific product for the specific country where the product is to be applied.

It has been found that for the antioxidant components, the amount present in the daily applied quantity of the food product is at least 3 times the recommended amount (RDA value from the Codex Alimentarius as is recommended in the Western countries). It is preferred to use amounts between

3 and 10 times the recommended amount (RDA value from the Codex Alimentarius) for those antioxidants of which such RDA values are available.

Determination of the amount of each of the antioxidants to be applied takes place by determination of the antioxidant level in the plasma of human beings after daily consumption of the average consumed amount of product after four weeks. The concentration in the blood plasma of the antioxidant applied is measured and compared to the concentration in the plasma of the antioxidant before the four weeks intake of the food product of the invention. In this specification, α-tocopherol, α- and β-carotene levels in plasma were measured using reversed phase HPLC. Ascorbic acid levels were determined by fluorimetric measurement using ascorbate oxidaze as described in "Fluorometric assay of vitamin C in biological materials using a centrifugal analyzer with fluorescence attachment", Vuilleumier JP, Keck E.J Micronutrient Analysis 1989;5:25-34. The method is to be carried out after treatment of fresh plasma with trichloroacetic acid. Other measurements are available as well, but provide less accurate results and due therefore not recommended. (E.g. spectrophotometric measurement, using enzymatic kits from Boehringer (Mannheim, Germany).

Antioxidants which are suitable to significantly increase the antioxidant level in the blood plasma are for example, α-tocopherol (vitamin E), ascorbic acid (vitamin C), polyphenol, and carotenoid such as α-carotene, B-carotene, lycopene, cryptoxanthin, zeaxanthin, and lutein.

The amounts indicated below are amounts per average daily applied amount of the food product it is used in.

In the case of α-tocopherol, the minimum amount to be used will be about 30 mg per amount, and preferably between 30 and 100 mg; for ascorbic acid, the minimum amount will be

about 100 mg, and preferably between 120 and 600 mg and further preferred between 180 and 600 mg; and for polyphenols obtained from tea, the minimum applied amount will be about 0.5 g, and preferably between 0.5 and 2.5 g. For other polyphenols, the minimum applied amount will be 25 mg, and preferably between 25 and 125 mg. For carotenoids, the amounts are 2 - 18 mg. It is to be noted here that carrots and maybe some other vegetables contain amounts within this range, but the carotenoids cannot be easily absorbed, and so are not capable of increasing the antioxidant levels in the blood plasma as now claimed. Preferably, the food product comprises 30-80 mg of α-tocopherol per amount of the average daily consumed amount of food product, and/or 120-600 mg and preferably 200-600 mg ascorbic acid, and/or 8-15 mg, preferably 10-15 mg of a (mixture of) carotenoid, and/or 0.7-2.0 g of a (mixture of) a tea polyphenol and/or 50-100 mg of a (mixture of) a polyphenol not being a polyphenol derived from tea. The food product of the invention suitably comprises at least 8 mg carotenoid, and preferably an amount between 8 and 18 mg per average daily applied amount of the food product. Preferably, the carotenoid is a mixture of α- and β-carotene. The use of a carotenoid has been found to show a very high increase in antioxidant level in the blood plasma.

Preferably, a mixture of at least two of the antioxidants is applied. In particular, it is preferred that the mixture comprises at least a water and a fat soluble antioxidant as applicants have some indications that the water soluble antioxidants are capable of regenerating the fat soluble antioxidants. Thus, food products comprising both water and fat soluble antioxidants are believed to be even more effective. At least, indications therefore for ascorbic acid and α-tocopherol have been noticed.

In a highly preferred embodiment, the food product is a yellow fat spread comprising 30-100 mg per 15 g of spread of α-tocopherol and/or derivatives thereof. More preferred is a spread in which at least both a water soluble and fat soluble antioxidant is present. For example, such a more preferred spread comprises per 15 g of spread 30-100 mg α-tocopherol and/or derivatives thereof, and 100-600 mg ascorbic acid.

Food products providing good benefits to the antioxidant level in the blood plasma, and, more in particular, to the reduction of the lipoprotein oxidation in vitro are for example tomato ketchup which comprises 30-100 mg α-tocopherol and/or derivatives thereof, and 100-600 mg ascorbic acid and 2-18 mg preferably 8-18 mg of a (mixture of) carotenoid, and yellow fat spreads having a fat level between 10 and 80 %, and comprising 30-100 mg of α-tocopherol and/or derivatives thereof, 120-600 mg of ascorbic acid and 8-18 mg of a (mixture of) carotenoid. All amounts indicated above are amounts per average daily consumed amount of the food product. It is preferred that such a spread comprises at least two thereof, preferably the two being α-tocopherol and ascorbic acid.

In another embodiment of the invention also polyphenol is present. Polyphenol is known as such, and has been described in different publications.
The term polyphenols (or phenolics) can be defined chemically as a substance which possesses an aromatic ring bearing one or more hydroxy substituents, including functional derivatives. Reference is made to "Phenolic Compounds in Food", Chi-Tang Ho; Phenolic Compounds in Food and Their Effects on Health II, Am. Chemical Soc., 1992 In this invention the term polyphenols refers to all plant phenolic molecules derived from a plant source with an antioxidant activity and not covered by the terms oryzanol, tocotrienol and tocopherol, e.g. simple phenols and

phenolic acids, hydroxycinnamic acid derivatives (e.g coumaric and ferulic acid) and flavonoids.

In the case of the food product of the invention being a fat based food product, the fat that is applied can be any fat, such as dairy fat and/or vegetable fat. However, if fat is present, for health reasons the use of one or more vegetable fat sources is preferred. In particular, the use of liquid fats is preferred. These can be hydrogenated, interesterified, and the like. The fat can be one single fat or a blend.

The use of fat compositions comprising a considerable amount of poly unsaturated fatty acid groups comprising triglycerides (pufa-triglycerides) in addition to the use of the antioxidants is in particular considered highly beneficial. For example, oils of sunflower, safflower, rapeseed, linseed, linola and/or soybean can be used in a preferred embodiment. Also the fat compositions mentioned in Netherlands patent documents no. Nl 143115, NL 178559, NL 155436, NL: 149687, NL 155177, European patent documents EP 41303, EP 209176, EP 249282, and EP 470658 are highly suitable.
If a fat blend is used, it is preferred that it comprises at least 30%, and more preferred at least 45% of poly-unsaturated fatty acids, based on the total weight amount of the fat in the fat based food product.
The fluorimetric method is used for analysing the ascorbic acid level.

Example

A spread was prepared comprising per 100 g of product 200 mg α-tocopherol , 840 mg ascorbic acid and 180 mg palm fruit carotenes (obtained from Quest, Naarden, Holland) (comprising about 18 mg α- and 36 mg β-carotene)

A control margarine of the same composition, with the proviso that no antioxidant was present, was prepared by the same method.

Measurement of the susceptibility of low density lipoprotein (lipoprotein) to oxidation *in vitro* was performed as follows.

Lipoprotein were isolated using density gradient ultracentrifugation. The formation of conjugated dienes during copper-mediated oxidation was monitored continuously at 234 nm. Before the start of the oxidation experiments the lipoprotein samples were diluted to give a final concentration of lipoprotein protein of 50 µg /ml in the assay cuvette. The incubation was carried out at 30°C. The final concentration of copper was 50 µM and that of EDTA 25 µM.

In a parallel comparison trial 31 healthy volunteers were randomised to consume normal daily quantities (15 g) of either a control margarine or a margarine enriched with moderate amounts of the antioxidants.
Per daily serving of antioxidant margarine, an intake of 31 mg α-tocopherol, 121 mg ascorbic acid and 8 mg palm fruit carotenes (comprising 5,3 mg beta carotene and 2,7 mg alpha carotene) was obtained. Before and after 4 weeks of margarine consumption, plasma antioxidant levels, total antioxidant activity of low density lipoprotein and the susceptibility of lipoprotein to oxidation in vitro were determined.

Determination of the total antioxidant activity of lipoprotein was performed as follows.
The method is based on the ability of antioxidants within lipoprotein to scavenge the $ATBS^{\cdot+}$ radical cation, as detected by a decrease in the absorbancy at 734 nm.

The assay was carried out using a Cobas Fara analyzer. In the protocol devised 250 µl of ATBS/myoglobin reagent in buffer was mixed with 50 µl of Trolox standard or lipoprotein preparation (1.13- 4.52 mg/ml lipoprotein protein), the pipette probe flushed with 20 µl water , then 20 µl of 3.125 mM hydroperoxide (followed by 10 µl of water to flush the probe) added to start the reaction. The incubation volume was thus 350 µl and the final concentrations were: 4.36 µM metmyoglobin, 436 µM ABTS, 180 µM hydrogen peroxide). The reaction was carried out at 30°C. A dose-response standard curve was derived using Trolox standards of 0, 2.86, 5.72, 8.58, 11.44, and 14.30 µM final concentration.

After consuming the antioxidant margarine for 4 weeks the mean plasma concentration of α-tocopherol increased siginifcantly by 14% ($P<0.005$) and that of plasma ascorbic acid by 10% ($P<0.001$) as compared to control group values. The plasma concentrations of β-carotene and α-carotene increase 3.4 fold and 14.5 fold, respectively ($P<0.0001$). Consumption of the fortified margarine significantly increased the resistance of lipoprotein to oxidation (+7%, $P<0.033$) as compared to baseline values. The total antioxidant activity of lipoprotein increased by 12% ($P<0.01$) with no significant increase being observed in the control margarine group. Measurements performed at baseline demonstrated a highly significant correlation between lipoprotein α-tocopherol levels and the lipoprotein total antioxidant activity ($r=0.87$, $P<0.0001$). It can be concluded the consumption of a margarine fortified with moderate amounts of antioxidants can be used to increase antioxidant status in the blood plasma and lipoprotein of healthy subjects.

Furthermore, it was found that the consumption of a margarine fortified with palm fruit carotenes delivers

alpha and beta-carotene to the body with high bioavailability.

Moderate antioxidant enrichment of foods may be an important means of achieving an optimal natural antioxidant status for the prevention of cardiovascular and other diseases.

Claims:

1. Food product comprising antioxidants and/or antioxidant vitamins in amounts sufficient to significantly increase the antioxidant status in the human blood plasma upon daily consumption of the daily average amount of the food product.

2. Food product according to claim 1, wherein the food product is a spread, dressing, sauce, ice cream or ketchup.

3. Food product according to anyone of claim 1 or 2, wherein the antioxidant is present in an amount of between 3 and 10 times the daily recommended amount (RDA value from the Codex Alimentarius) per average daily amount of food product consumed.

4. Food product according to anyone of claims 1 to 3, wherein the antioxidant is chosen from the group consisting of α-tocopherol (vitamin E), ascorbic acid (vitamin C), polyphenol, and carotenoid such as α-carotene, β-carotene, lycopene, cryptoxanthin, zeaxanthin, and lutein, or mixtures thereof.

5. Food product according to claim 4, wherein the food product comprises 30-100 mg of α-tocopherol per amount of the average daily consumed amount of food product, and/or 120-600 mg ascorbic acid, and/or 2-18 mg of a (mixture of) carotenoid, and/or 0.5-2.5 g of a (mixture of) a tea polyphenol and/or 25-125 mg of a (mixture of) a polyphenol not being a polyphenol derived from tea.

6. Food product according to any one of the claims 1-5, wherein a mixture of at least two antioxidants is used.

7. Food product according to claim 6, wherein at least one water soluble antioxidant or antioxidant vitamin and at

least on fat soluble antioxidant or antioxidant vitamin is used.

8. Food product according to any one of claims 1-7, wherein the food product is a yellow fat spread comprising per average daily amount of spread used 30-100 mg α-tocopherol and/or derivatives thereof, 100-600 mg ascorbic acid and 2-18 mg palm fruit carotenes.

9. Food product according to claim 8, wherein the food product is a spread having a fat level between 5 and 80%, and the fat comprises at least 45% of polyunsaturated fatty acids.

10. Use of an antioxidant or antioxidant vitamin for the preparation of a food product according to any one of the claims 1 to 9.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 96/03379

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A23L1/00 A23L1/24 A23D7/00 A23C13/12 A23C15/12
A23C19/09 A23L1/302 A23L1/303 A23G9/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A23L A23D A23C A23G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,92 10941 (UNILEVER PLC ET AL.) 9 July 1992 see page 7, line 15 - page 8, line 2 ---	1,2,4,8, 10
X	EP,A,0 561 744 (SIRC S.P.A. NATURAL & DIETETIC FOODS) 22 September 1993 see page 3, line 49 - page 4, line 8 ---	1
A	DE,A,19 24 465 (HANS WEIDEMANN) 19 November 1970 see page 2, line 24 - line 29; claims 1,2,4 ---	1-10
A	WO,A,95 05747 (THE PILLSBURY COMPANY) 2 March 1995 see page 4, line 15 - page 5, line 5 --- -/--	1-10

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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Date of the actual completion of the international search	Date of mailing of the international search report
12 November 1996	04. 12. 96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Alvarez Alvarez, C

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR,A,2 704 397 (BOIRON S.A.) 4 November 1994 see page 3, line 16 - line 26 see page 4, line 1 - line 24 see claim 1	1
A	GB,A,2 151 123 (SOCIETE DES PRODUITS NESTLE S.A.) 17 July 1985 see abstract	1,4-6

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 96/03379

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9210941	09-07-92	AU-A-	8904391	22-07-92
		ZA-A-	9110003	21-06-93
EP-A-561744	22-09-93	IT-B-	1254311	14-09-95
		BR-A-	9301193	28-09-93
		CA-A-	2081280	21-09-93
		JP-A-	5336923	21-12-93
DE-A-1924465	19-11-70	NONE		
WO-A-9505747	02-03-95	AU-A-	7633194	21-03-95
FR-A-2704397	04-11-94	NONE		
GB-A-2151123	17-07-85	AU-B-	588500	14-09-89
		AU-A-	1285288	23-06-88
		AU-B-	571289	14-04-88
		AU-A-	3649284	20-06-85
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		DE-A-	3485582	16-04-92
		EP-A-	0169936	05-02-86
		EP-A-	0267630	18-05-88
		JP-C-	1367939	11-03-87
		JP-A-	60145076	31-07-85
		JP-B-	61034792	09-08-86
		US-A-	4891231	02-01-90
		US-A-	4925681	15-05-90
		OA-A-	7935	31-01-87
		US-A-	4839187	13-06-89

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

To:
UNILEVER N.V.
Patent Department
Attn. Sikken, Antonius J.H.M
Olivier van Noortlaan 120
NL-3133 AT Vlaardingen
NETHERLANDS

AHS

Applicant's or agent's file reference F 7478 (V)	Date of mailing *(day/month/year)* 27/06/2000
International application No. PCT/EP 99/09563	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
Applicant UNILEVER N.V et al	International filing date *(day/month/year)* 02/12/1999

1. [X] The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Raffaella Boero

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international pbulication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped),whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international appplication is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.